

### REMARKS

This paper responds to the Office Action mailed on January 28, 2004.

Claims 26, 27, and 30 are amended, no claims are canceled, and claim 44-45 are added; as a result, claims 1-19 and 25-45 are now pending in this application.

#### Telephone Interview Request

Applicant requests a telephone interview with the examiner if the application is not allowed in the next communication from the USPTO. The examiner can call the undersigned at 612-349-9587. The undersigned believes that such an interview will assist in moving this application to allowance or, at a minimum clarify issues for appeal.

#### §112 Rejection of the Claims

Claims 31, 33, 35, 38-40 were rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses.

Claim 31 was rejected based on its recitation of “micro-structured heating elements include nickel-chromium thick film resistance heaters”, see Office Action page 3. The originally filed specification supports claim 31, for example, at page 14, lines 9-13. Withdrawal of this rejection is requested.

Claim 33 recites “wherein the microstructured temperature sensors include nickel-chromium thick film resistance sensors.” The originally filed specification supports claim 33, for example at page 14, lines 9-13. Withdrawal of this rejection is requested.

Claim 35 was rejected based on its recitation of “chamber body further includes an additional sealing surface adapted to releasably connect to the chamber support.”, see Office Action page 3. The originally filed specification supports claim 35, for example, at page 18, lines 20-23, Fig. 13, and originally filed claim 14. Withdrawal of this rejection is requested.

Claim 38 was rejected based on its recitation of “at least one of antibodies, receptor molecules, hormones and pharmaceutically active peptides”, see Office Action page 3. The originally filed specification supports claim 38, for example, at page 12, lines 12-14 and originally filed claim 17. Withdrawal of this rejection is requested.

Claim 39 was rejected based on its recitation of “transmitted-light fluorescence measurement, dark field fluorescence measurement, confocal fluorescence measurement, reflected-light fluorescence measurement, photometry and differential photometry”, see Office Action page 3. The originally filed specification supports claim 39, for example, at page 15, lines 1-2, lines 6-8; page 18, lines 20-29; page 19, lines 5-13; and originally filed claim 18. Withdrawal of this rejection is requested.

Claim 40 was rejected based on its recitation of “capillary gap is adapted to provide almost simultaneous performance of a chip-based characterization and at least one reprocessing reactions and conditioning reactions”, see Office Action page 3. The originally filed specification supports claim 39, for example, at page 10, lines 1-5, lines 6-8; page 24, lines 4-6; and originally filed claim 19. Withdrawal of this rejection is requested.

Applicant submits that at least the above provide support for claims 31, 33, 35, 38-40. However, the above specific citations to the present application may not be the only places where support may be found. No claim is amended in response to these rejections. Reconsideration and withdrawal of these under 35 USC § 112, first paragraph rejections is requested.

#### §102 Rejection of the Claims

Claims 1-5, 8-10, 12-15, 17-19, 25-36 and 38-43 were rejected under 35 USC § 102(b) as being anticipated by Lipshutz et al. (US 5,856,174). Applicant respectfully traverses.

Independent claim 1 recites, in part, “the capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein.” Applicant can not find these features in Lipshutz. In fact Lipshutz teaches that the amplification and characterization occur in distinct chambers.

The Office Action at page 7 states that

the device of Lipshutz comprises a chamber boy and optically permeable support sealed together to form a capillary gap (ie well or cavity space forming the reaction chamber between the body and support, Column 15, lines 14-17) whereby the gap forms a single reaction chamber.

Lipshutz at Column 15, lines 9-20 states

As an example, the wells manufactured into the surface of one planar member make up the various reaction chambers of the device. Channels manufactured into the surface of this or another planar member make up fluid channels which are used to fluidly connect the various reaction chambers. Another planar member is then placed over and bonded to the first, whereby the wells in the first planar member define cavities within the body of the device which cavities are the various reaction chambers of the device.

Similarly, fluid channels manufactured in the surface of one planar member, when covered with a second planar member define fluid passages through the body of the device (emphasis added).

Accordingly, Lipshutz requires various, that is, a plurality of reaction chambers. The question now is does Lipshutz teach that any single one of its various reaction chambers is adapted to amplify and characterize nucleic acids therein. Applicant submits that Lipshutz does not teach this feature of claim 1.

Lipshutz at col. 2, lines 23-27 states “a fluid transport system for moving a fluid sample from at least a *first reaction chamber* of said plurality of reaction chambers to at least a *second reaction chamber* of said plurality of reaction chambers and a *hybridization chamber* for analyzing a component of said fluid sample (emphasis added).” Accordingly, Lipshutz here teaches at least two reaction chambers and a further hybridization chamber. This is not a capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein as recited in claim 1.

Lipshutz at col. 4, lines 22-25 states

one embodiment of the device of the invention will incorporate a *plurality of distinct reaction chambers* for carrying out the sample acquisition, preparation and analysis operations. In particular, a sample to be analyzed is introduced into the device whereupon it

will be *delivered to one of several distinct reaction chambers* which are designed for carrying out a variety of reactions as a *prelude* to analysis of the sample (emphasis added).

Here Lipshutz teaches that a plurality of reaction chambers carry out a variety of reactions.

Lipshutz does not teach that any of its variety of chambers performs both reaction and analysis of a sample. In contrast, claim 1, recites “the capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein.”

Lipshutz at col. 17, lines 51-60 states

the device may incorporate a *plurality* of reaction chambers, storage chambers and analytical chambers, arranged in *series*, whereby a fluid sample is moved serially through the chambers, and the *respective operations* performed in these chambers.

Alternatively, the device may incorporate a *central chamber* having the *various reaction/storage/analytical chambers* arranged around and fluidly connected to the central chamber, which central chamber acts as a sample gathering and redistribution hub for these various chambers (emphasis added).

Accordingly, Lipshutz does not here teach the capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein as recited in claim 1.

Lipshutz at col. 33, lines 29-31, claim recites a body having at least a *first reaction chamber* fluidly connected to a *second reaction chamber*.

Claim 1 recites, in part, “which the chamber body is sealingly placed to form a capillary gap between the chamber support and the detection area of the chip the capillary gap being temperature-adjustable and flow-controllable, and wherein the capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein.” Applicant can not find these features in Lipshutz. For example, claim 1 recites the capillary gap forms a single reaction chamber and is adapted to amplify and characterize nucleic acids therein.

Lipshutz does not teach such a feature. In fact, Lipshutz teaches a plurality of distinct reaction chambers, see e.g., col. 2, lines 16-20, Fig. 3, Figs. 5A, 5B, 6A and 6B along with the related text of Lipshutz. Still further, the Office Action admits that Lipshutz teaches that samples are put into one reaction chamber of the device and transferred to subsequent reaction chambers via fluid channels for controlled sample processing, fluid flow and nucleic acid amplification via

temperature adjustments. Moreover, applicant can not find where Lipshutz teaches or even suggests that a capillary gap is adapted to amplify and characterize nucleic acids as recited in claim 1.

Independent claim 1 also recites a “capillary gap”. Applicant can not find this feature in Lipshutz. A capillary cap is of extremely small dimensions. The term “capillary” is defined as of or relating to a tube with a fine bore. Oxford Dictionary of Biochemistry and Molecular Biology, 1997, copy attached hereto. Hence even minimal amounts of a sample can be used. Moreover, the extremely small dimensions of the capillary gap provide numerous control benefits that the common PCR chambers of Lipshutz does not provide. Applicant can not find capillary gaps as defined by claim 1 in Lipshutz.

Based at least on the foregoing, applicant submits that claim 1 and claims 2-19 and 25-43 depending therefrom are allowable over Lipshutz. Reconsideration and allowance are requested.

The Office Action refers to column 19, lines 1-15 and column 24, line 34 – Column 25, line 41 of Lipshutz as teaching the subject matter of claim 2. Applicant can not find in this cited portion of Lipshutz any reference to a temperature adjustment means connected with the chamber support and adapted to permit a rapid temperature control the *capillary gap* as recited in claim 2. Reconsideration and allowance of claim 2 are requested.

Independent claim 25 recites, in part, “a capillary gap intermediate the chamber support and the chamber body, the capillary gap being adapted to act as a single chamber for both the reaction and characterization of nucleic acids.” Applicant can not find these features in Lipshutz. In fact Lipshutz teaches that the amplification and characterization occur in distinct chambers.

The Office Action at page 8 states that

Lipshutz et al. disclose . . . a capillary gap intermediate the support and body, the gap adapted to act as a single chamber for both reaction (e.g. hybridization) and characterization (detection) of nucleic acids (e.g. Fig. 7A, Column 15, lines 9-34; and Column 19, lines 1-15 and column 24, line 34-Column 24, line 41).

Applicant traverses. As stated above Lipshutz merely teaches a plurality of reaction chambers each performing various functions. Applicant can not find in the cited portions of Lipshutz a teaching of capillary gap that is adapted to act as a single chamber for both the reaction and

characterization of nucleic acids as recited in claim 25. Applicant requests a specific cite to where Lipshutz shows a capillary gap that acts as a single chamber for both reaction and characterization.

Applicant requests allowance of claim 25 and its dependent claims 26-30.

§103 Rejection of the Claims

Claims 6 and 7 were rejected under 35 USC § 103(a) as being unpatentable over Lipshutz et al. (US 5,856,174) in view of McBride et al. (US 6,296,752) as defined by *Academic Press Dictionary of Science and Technology* (Academic Press, San Diego, 1992, page 1768). Claim 11 was rejected under 35 USC § 103(a) as being unpatentable over Lipshutz et al. (US 5,856,174) in view of Atwood et al. (US 5,475,610). Claims 16, 17 and 37 were rejected under 35 USC § 103(a) as being unpatentable over Lipshutz et al. (US 5,856,174) in view of Fodor et al. (US 5,744,101). Applicant respectfully traverses as none of the secondary documents account for the deficiencies of Lipschutz as a reference under 35 USC §§ 102 and 103.

Applicant further incorporates the prior response by reference in its entirety to preserve all issues for appeal.

## CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 349-9587 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,  
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Date

26 July 2004

By

  
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 26th day of July, 2004.

PATRICIA A. HULTMAN

Name

  
Signature